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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,217	11/29/1999	PETER ERDMANN	8265-296-999	7310

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	15

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/450,217	Erdmann
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 15, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above, claim(s) *14-19 and 21-23* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13 and 20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Pursuant to the directives of paper No. 14 (filed 2/15/02), claims 1, 3-6, 9-10, 12, 13 have been amended, and claim 23 added. Claims 1-23 remain pending.

Claims 14-19 and 21-23 remain withdrawn from consideration.

Applicants' arguments filed 2/15/02 have been considered and found not persuasive with regard to the §103 rejection.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The cited claims do not require isolation of the GMP. The question then arises, how does one use the GMP if it is never isolated? If it is present in a mixture with other materials, and present in a container from which it is never removed, how does one proceed? The specification provides no guidance in this regard. It is suggested that the claims be amended to require isolation (or recovery) of the GMP.

*

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 20 recites that GMP exhibits efficacy in the treatment of diarrhea and bacterial infections. However, there is no evidence that this is the case. The reality is that treatment of infectious disease is a daunting proposition even when *in vitro* data is obtained. But when one merely selects compounds at random, the likelihood of success is vanishingly small. If it has been disclosed in the prior art that GMP is effective to treat diarrhea or bacterial infections, it is suggested that applicants bring such to the fore. Alternatively, it is suggested that claim 20 be amended to delete recitation of diarrhea and bacterial infections.

*

Claims 1-13 and 20 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 remains indefinite because of its failure to recite a step for isolation of the final product. Claim 1 does recite "removing GMP". However, this is not the same as isolating or recovering. Moreover, it is not clear exactly what is intended by "removing". Does this mean that pure, dry GMP is "removed", or does it mean

that an aqueous composition containing GMP is removed? If the claim only provides process steps for obtaining an aqueous mixture that contains GMP, it is suggested that the claim be drawn instead to a process for preparing a mixture that contains GMP, rather than to a process for preparing GMP *per se*. In claim 12, the issue is related. This claim recites the phrase "recovering the GMP as the retentate". Here again, the retentate is an aqueous solution. If the process only provides the means to obtain an aqueous solution, it is suggested that the claim be amended to recite this as an objective. Better yet would be to add a step for isolating or recovering the GMP.

- Claim 4 is somewhat confusing. This claim mandates adding calcium ions to deionized lactic raw material. However, if one takes a deionized material, and adds ions to it, the result is that one has an ionized material, rather than a deionized one. Accordingly, there appears to be a contradiction. It is suggested that claim 4 be written in independent form. The issue in the case of claim 5 is related. Claim 5 mandates the use of an alkaline material; claim 1, on the other hand, mandates that the pH of the lactic raw material be no higher than 4.5. Thus, once in possession of the lactic raw material having a pH of 4.5, if one adds an "alkaline material" such as NaOH, the result will be that the pH will then exceed 4.5. Thus, there is a contradiction. Is the upper limit of the pH 4.5, or is the upper limit greater than 4.5...? It is suggested that claim 5 be written in independent form.

- Claim 20 is dependent on a non-elected claim, and moreover, the term "composition" lacks antecedent basis. It is suggested that claim 20 be written in independent form; a format such as the following could be used:

A process for preparation of a composition that contains caseinoglycomacropeptide in combination with a pharmaceutically acceptable carrier, said process comprising:

(a) deionizing a lactic raw material...

(b) contacting the substantially deionized lactic raw material...

(c) separating the resin...

(d) recovering the GMP... and

(e) combining the GMP of step (d) with a pharmaceutically acceptable carrier.

- In claim 3, the phrase "about 10 - 23 %" is recited. This renders the claim indefinite as to the upper and lower limits. It is suggested that the word "about" be deleted.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3, 5-13 are rejected under 35 U.S.C. §103 as being unpatentable over Shimatani (USP 5,434,250).

As indicated previously, Shimatani teaches (beginning at col 2, line 67) a process of obtaining GMP by passing desalted whey, at acidic pH, through a cation exchanger. Additionally, claim 5 of the patent (col 6, line 23+) teaches a process of obtaining GMP by passing whey, at acidic pH, through a cation exchanger, and then employing the further step of ultrafiltration.

Applicants have traversed by arguing that the reference teaches a process for obtaining

sialic acids, rather than GMP. However, the disclosure is replete with references to GMP. It may be true that the reference does not emphasize the desirability of recovering, and subsequently using the GMP, but the reference teaches a process that results in the separation of GMP from the other components.

Applicants have also argued that Shimatani does not disclose acidifying whey to a pH of 2-5. However, this is taught at col 2, line 67-68. Applicants have also argued that Shimatani does not disclose contacting the whey with an anionic resin. However, cation exchange resins are resins which bear anionic groups. As disclosed at col 3, line 21, anionic groups are present. (See also Scopes, "Protein Purification", pages 75-101, which is of record). Applicants have also argued that the reference does not disclose that the chromatographic matrix should be separated from the desired final product. However, the chromatographic specialist of ordinary skill is well aware that the purpose of the chromatographic matrix is to achieve separation, and that the intended product should be separated from the chromatographic matrix. The chromatographic matrices which are commercially available are not soluble in water, and are not soluble in most organic solvents. The purpose of this is to permit facile separation of the products which have passed through the chromatographic matrix. The chromatographic specialist of ordinary skill is required to have, and does have, a level of sophistication which goes well beyond this basic information. In any case, however, the reference does disclose (e.g., col 4, line 23+) the

procedure of separating the chromatograhic matrix from the intended product.

Applicants have also argued that the reference does not teach separation of, or acquisition of, GMP. However, this is taught, for example, at col 3, line 11. It is true that the emphasis of the reference is on obtaining alpha-lactalbumin, but the reference affirmatively discloses the presence of the GMP, as well as the means to obtain it.

The rejection is maintained.

*

Claims 1-3 and 5-13 are rejected under 35 U.S.C. §103 as being unpatentable over Shimatani (USP 5,434,250) in view of Marshall (*Food Research Quarterly* **51**, 1991, reference "AL" on the IDS).

The teachings of Shimatani and Marshall were indicated previously. Applicants have not traversed this rejection, other than to imply that Shimanti taken by itself is inadequate, and that therefore Shimatani in view of Marshall must be inadequate as well. However, the major basis of traversal of the Shimatani reference is that, while Shimatani may disclose the presence of GMP, the reference does not provide motivation to actually use the GMP, as opposed to discarding it. However, given the teachings of Marshall, there is clear motivation to use the GMP; Shimatani provides the technical means to isolate it. It is suggested that in further traversing, applicants provide reasons why a person who is clearly motivated to isolate and use GMP would not be able to do so, given the teachings of

Shimatani. If such reasons can be provided, it may help to advance the prosecution.

Thus, the claims are rendered obvious.

*

Claims 1-3, 5-13 are rejected under 35 U.S.C. §103 as being unpatentable over Kawasaki (USP 5278288)

Kawasaki discloses (col 2, line 62+) a process of preparing GMP by contacting milk raw materials with a cation exchanger. The recommended pH is in the range of 3-4.5 (col 3, line 62+) . Also, in example 1 (col 6, line 3+) a pH of 4.0 was usd in conjunction with an anionic resin. The reference suggests collecting a fraction which does not adsorb on the anionic resin; however, this meets the limitations of the claims which require only "removal" of the GMP from the lactic raw material.

Thus, the claims are rendered obvious.

*

Claim 20 is rejected under 35 U.S.C. §103 as being unpatentable over Shimatani (USP 5,434,250) in view of Drouet (USP 5,063,203).

The teachings of Shimanti were indicated previously. Shimatani does not disclose that GMP inhibits thrombosis. Drouet discloses that GMP inhibits thrombosis, but does not disclose the claimed process.

Thus, it would have been obvious to one of ordinary skill at the time of the invention to

combine the GMP with a pharmaceutically acceptable carrier in order to obtain a composition which inhibits thrombosis.

*

Claim 20 is rejected under 35 U.S.C. §103 as being unpatentable over Kawasaki (USP 5,278,288) in view of Drouet (USP 5,063,203).

The teachings of Kawasaki are indicated above. Kawasaki does not disclose that GMP inhibits thrombosis. Drouet discloses that GMP inhibits thrombosis, but does not disclose the claimed process.

Thus, it would have been obvious to one of ordinary skill at the time of the invention to combine the GMP with a pharmaceutically acceptable carrier in order to obtain a composition which inhibits thrombosis.

*

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600